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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,307	03/16/2004	Todd Robida	03-183	1975
27774 7590 12/26/2006 MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090			EXAMINER BOECKMANN, JASON J	
			ART UNIT 3752	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/801,307	Applicant(s) ROBIDA, TODD	
	Examiner Jason J. Boeckmann	Art Unit 3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10/10/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings were received on 10/10/2006. These drawings are not accepted, see rejections below and on the attached PTO-948 form.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, two valve seats of claims 1, 2, 5, 6, 11, 19 and 20, and the first position, second position and the default neutral position of the valve, and the must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In response to the applicant's argument, the examiner is objecting to the drawings under rule 37 CFR 1.83(a), not 37 CFR 1.81, which clearly states that every feature of the invention specified in the claims must be shown in the drawings. The neutral position of the valve is not shown in figure 11 nor does the specification indicate that figure 11 represents the neutral position of the valve. Furthermore, the expanded and annotated figure on page 14 of the remarks is not part of the applicant's disclosure and therefore is not considered. Regarding the new drawings 17a, 17b and 17c, a schematic drawing cannot represent the open and closed positions of the valve when only details of relative positions of the internal parts and features of the valve can clearly show the respective positions. From the figures, it is unclear what the specific valve looks like in each of the three positions listed above and what features of the valve move with respect to the valve body when it switches between each of the three positions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 11 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Examiner is unsure of how the valve returns to its neutral state without the use of a spring return mechanism. There is no disclosure of any internal parts or features to the valve that indicate how it would return to a default neutral state when the supply pressure operating the valve is removed, nor does the specification explain how the valve returns to its neutral state.

In response to the applicant's arguments, It is still unclear as to how the valve is biased toward a neutral position in there is no spring mechanism to bias it that way. If the valve of the present invention is in the open position, and the pneumatic force is removed from the valve, what allows the valve to move back to the neutral position?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4, 5, 7, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figure 1) in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (70), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device being adapted to withdraw the coating solution from the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve (70) and through the solution outlet (12). The admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats. However, Kintner shows a pneumatic actuated three-way valve (figure 3) with no spring return mechanism, comprising first (22), second (23) and third (24) valve ports, two pneumatic ports (8 and 6), and two valve seats (13, 14, 15). It would have been obvious to one of ordinary skill in the art at the time of the

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applicant's invention to substitute the new pneumatically actuated three-way valve of Kintner for the three-way valve of figure 1 in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 4, 12 and 13, the solution receptacle comprises a syringe (14) and the solution outlet comprises a spray nozzle (12).

Regarding claim 7, the medical device of the admitted prior art as modified by Kintner includes a first tube (13a) having a first diameter coupled to the first port (8) and a second tube (13c) having a second diameter coupled to the second port (6).

Regarding claim 10, the medical device of the admitted prior art as modified by Kintner includes one or more disposable fittings (16a, 16b, 16c, 16d).

Claims 1-7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liston (3,817,425) in view of Kintner (3,426,799).

Liston discloses a medical device coating unit comprising a three-way valve (300), a solution reservoir (272) connected to a first port (305), a solution receptacle (291) connected to a second port (307), and a solution outlet (226) connected to a third port (306). The medical device being adapted to withdraw the coating solution from the reservoir (272) through the valve (300) and into the solution receptacle (291) and expel the coating material from the solution receptacle (291) through the valve (300) and through the solution outlet (226). Liston does not specifically disclose that the valve is a

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pneumatic actuated three-way valve with no spring return mechanism and two valve seats. However, Kintner shows a pneumatically actuated three-way valve (figure 3) with no spring return mechanism, comprising first (22), second (23) and third (24) valve ports, two pneumatic ports (8 and 6) and two valve seats (13, 14, 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the new pneumatic actuated three-way valve of Kintner for the three-way valve of Liston in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.

Regarding claims 2 and 11, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claim 7, the medical device of Liston as modified by Kintner includes a first tube (275) having a first diameter coupled to the first port (305) and a second tube (298) having a second diameter coupled to the second port (307).

Claims 1, 3 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figures 1-8) in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (20 the prior art valve with the spring return mechanism), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device

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being adapted to withdraw the coating solution from the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve (70) and through the solution outlet (12), the three way valve comprising two valve seats and an air pressure diaphragm. The admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve comprising two air pressure diaphragms and with no spring return mechanism.

However, Kintner shows a pneumatic actuated valve that has a pneumatic port on one end, to move the valve assembly to the open position, and either a spring return mechanism (figures 5 and 5) or another pneumatic port on the other end (figure 4), to move the valve assembly to the closed position, therefore, Kintner teaches that a pneumatic port can be interchangeable with a return spring mechanism.

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to replace the spring return mechanism of the admitted prior art valve with a pneumatic port, including an air pressure diaphragm, in order to move the valve assembly in the opposite direction as the already existing pneumatic port and air pressure diaphragm, as taught by Kintner. This modification would give the valve more accuracy in positioning the valve assembly between the two valve seats.

Regarding claims 6 and 20, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range

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of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve from the first position to the second position more accurately.

With respect to claims 14-18, the use of the apparatus of the applicant's admitted prior art, as modified by Kintner, inherently performs the steps and methods of the claims.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figures 1-8), in view of Kintner (3,426,799) further in view of Chemline Plastics Ltd. (2001).

The applicant's admitted prior art as modified by Kintner shows all aspects of the applicant's invention as in claim 5, including threaded inserts (14, 15, 16), but does not specifically disclose that it contains stainless steel threaded inserts. However, Chemline Plastics Ltd. shows a pneumatic valve with stainless steel threaded inserts (page 2). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the stainless steel threaded inserts of Chemline Ltd. for the threaded inserts of the applicant's admitted prior art as modified by Brown, in order to prevent corrosion. Additionally, it is well known that stainless steel is an obvious choice of material for medical devices due to its ability to resist corrosion and be easily cleaned. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel in order to prevent corrosion.

In addition, It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of design choice (In re Leshin, 125 USPQ 416).

Response to Arguments

Applicant's arguments filed 10/10/2006 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation for replacing the spring return mechanism with the second pneumatic port would have been in the knowledge generally available to one of ordinary skill in the art. Adding the second pneumatic port allows for the valve to be operated at higher pressures therefore giving to greater accuracy in positioning the valve assembly between the two valve seats.

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Regarding claims 2 and 11, it appears that the present invention disclosed no means for returning the valve to the neutral position after it is in either the open position or the closed position and the actuating air is removed. The valve of Kintner appears to perform in the same manor.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eggleston (862,867) teaches that a pneumatic piston and a pneumatic diaphragm are interchangeable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason J. Boeckmann whose telephone number is (571) 272-2708. The examiner can normally be reached on 7:30 - 5:00 m-f, first Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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12/14/08


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